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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appln. No.	:	10/749,046	Confirmation No. 7407
Applicant	:	William J. Boyle et al.	
Filed	:	December 29, 2003	
Art Unit	:	3762	
Examiner	:	Moulton, Elizabeth Rose	
Title	:	EMBOLIC PROTECTION DEVICES	
Docket No.:	:	ACSES-66147 (G1738USC1)	
Customer No.	:	24201	June 19, 2009

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is being filed pursuant to the Notice of Appeal filed on September 15, 2008 and the Notice of Panel Decision from Pre-Appeal Brief dated May 21, 2009. This Appeal Brief is being filed within one (1) month of the date of the Notice of Panel Decision from Pre-Appeal Brief Review.

INTRODUCTION

The present invention relates to a filter element used to help in the loading and retrieval of embolic debris generated, for example, when a stenting procedure is being performed in an artery. The filter element includes a central region having an inlet opening and a storage reservoir for capturing the embolic debris. The central region includes a plurality of openings adapted to allow blood to flow therethrough but small enough to capture embolic debris larger than the size of the openings to contain the debris within the reservoir. The filter element includes a filter edge integral with a central region and also has an inlet opening. The claimed filter element is directed to the flexible membrane used to capture and collect embolic material entrained in body fluids. For this reason, all of the claims contain the recitation that the central region and filter edge are made from a filter membrane.

In use, the filter element is adapted to move from an expanded position to a collapsed position by sliding a restraining sheath initially over the **filter edge** and thereafter over the central region to move at least a portion of the filter element into the restraining sheath. The filter edge is configured similar to a crown, with a pattern of staggered alternation peaks and valleys that allow the **filter edge** to be incrementally introduced into the restraining sheath, thus preventing the filter membrane from entering the sheath all at once. Each valley region has a particular "depth" and each peak region has a particular "height" with at least two peak regions have different heights. As the filter membrane is being loaded or retrieved, the longer peaks of the filter edge would enter the restraining sheath first and the shorter peaks would enter the sheath, accordingly, later to prevent bunching of the filter edge.

The present application, U.S. Serial No. 10/749,046, was filed on December 29, 2003 and is a continuation application of Serial No. 09/476,159 filed on December 30, 1999, which is now U.S. Patent No. 6,695,813.

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is ABBOTT CARDIOVASCULAR SYSTEMS INC. (formerly Advanced Cardiovascular Systems, Inc., the assignee of record), 3200 Lakeside Drive, Santa Clara, CA 95054, which is a division of Abbott Laboratories, 100 Abbott Park Road, Abbott Park, Illinois 60664-3500. This application was originally assigned by the inventors, WILLIAM J. BOYLE, DAVID H. BURKETT, ANDY E. DENISON, BENJAMIN C. HUTER, SCOTT J. HUTER, ARKADY KOKISH, KENT B. STALKER, CHICHENG WANG and JOHN D. WHITFIELD to ADVANCED CARDIOVASCULAR SYSTEMS, INC., by Assignment executed on May 15, 2000, which was recorded by the U.S. Patent Office on May 19, 2000 beginning at Reel 010835, Frame 0835.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly effect, or be directly effected by, or have a bearing on the Board's decision on this appeal, it is to be noted that is believed there are no such appeals or interferences known to the Appellant.

III. STATUS OF CLAIMS

The status of the claims in this application is:

A. Total Number of Claims in the Application

The claims in the application are: Claims 94-116.

B. Status of All Claims on Appeal

Claims 94-116 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,152,946 to Broome et al. (the "Broome patent") in view of U.S. Patent No. 5,800,457 to Gelbfish (the "Gelbfish patent).

C. Claims on Appeals

The claims on appeal are each of pending claims 94-116. A copy of the claims being appealed is appended as Exhibit 1.

IV. STATUS OF AMENDMENTS

On September 15, 2008, the Examiner issued a final Office Action maintaining the §103 rejections of the pending claims. The finally rejected claims attached to this brief are the subject of this appeal.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Claims 94 to 113 are directed to the filter element which constitutes the filter membrane only. Claims 114-116 are directed to the combination of a frame assembly and a filter element made from a filter membrane.

Independent Claim 94

Independent claim 94 is supported in the drawings and specification as follows:

94. (Previously Presented) A filter element (page 40, lines 12-14; FIGS. 41 & 42; #570), for capturing embolic debris released into the bloodstream of a blood vessel of a patient, comprising:

a central region (page 40, lines 14-16; FIGS. 41 & 42; # 574) having an inlet opening and defining a storage reservoir for capturing embolic debris, the central region having a plurality of openings (page 40, lines 14-16; FIGS. 41 & 42;

576) adapted to allow blood to flow therethrough but capture embolic debris larger than the size of the openings and contain the debris within the reservoir; and

a filter edge (page 40, lines 16-20; FIGS. 41 & 42; # 572) integral with the central region and having an inlet opening, the filter element being adapted to move from an expanded position to a collapsed position by sliding a restraining sheath initially over the filter edge and thereafter over the central region to move at least a portion of the filter element into the restraining sheath, the filter edge having a pattern of alternating peak regions (page 40, lines 16-24; FIGS. 41 &42; #578) and valley regions (page 40, lines 16-24; FIGS. 41 & 42; # 580) which prevent the filter edge from entering into the restraining sheath all at one time, wherein each valley region has a particular depth (page 41, lines 5-16; FIG. 42) and each peak region has a particular height (page 41, lines 5-16; FIG. 42) and at least two peak regions have different heights and the central region and filter edge are made from a filter membrane.

Independent Claim 101

Independent claim 101 is supported by the drawings and specification as follows:

101. (Previously Presented) A filter element page 40, lines 12-14; FIGS. 41 & 42; #570) for capturing embolic debris released into a body vessel, comprising:

a central region (page 40, lines 14-16; FIGS. 41 & 42; # 574) having an inlet opening and defining a storage reservoir for capturing embolic debris, the central region having a plurality of openings(page 40, lines 14-16; FIGS. 41 & 42; # 576); and

a filter edge (page 40, lines 16-20; FIGS. 41 & 42; # 572) integral with the central region and having an inlet opening, the filter element being adapted to

move from an expanded position to a collapsed position by sliding a restraining sheath initially over the filter edge and thereafter over the central region to move at least a portion of the filter element into the restraining sheath, the filter edge having a pattern of alternating peak regions (page 40, lines 16-24; FIGS. 41 &42; #578) and valley regions (page 40, lines 16-24; FIGS. 41 & 42; # 580), wherein each valley region has a particular depth (page 41, lines 5-16; FIG. 42) and each peak region has a particular height (page 41, lines 5-16; FIG. 42), at least two peak region having different heights and each valley region has a round configuration which reduces stress concentration at the valley region and the central region and filter edge are made from a filter membrane.

Independent Claim 105

Independent claim 105 is supported by the drawings and specification as follows:

105. (Previously Presented) A filter element page 40, lines 12-14; FIGS. 41 & 42; #570) for capturing embolic debris released into a body vessel, comprising:

a central region (page 40, lines 14-16; FIGS. 41 & 42; # 574) having an inlet opening and defining a storage reservoir for capturing embolic debris, the central region having a plurality of openings (page 40, lines 14-16; FIGS. 41 & 42; # 576); and

a filter edge (page 40, lines 16-20; FIGS. 41 & 42; # 572) integral with the central region and having an inlet opening, the filter element being adapted to move from an expanded position to a collapsed position by initially drawing the filter edge into the catheter and thereafter the central region to move at least a portion of the filter element into the catheter, the filter edge having a sinusoidal pattern of alternating peak regions (page 40, lines 16-24; FIGS. 41 &42; #578) and

valley regions (page 40, lines 16-24; FIGS. 41 & 42; # 580), wherein the filter element can be drawn into the catheter and the valley regions are staggered so that no two valley regions enter the catheter at the same time and the central region and filter edge are made from a filter membrane.

Independent Claim 114

Independent claim 114 is supported by the drawings and specification as follows:

114. (Previously Presented) A filter assembly page 40, lines 12-14; FIGS. 41 & 42; #570) for capturing embolic debris released into the bloodstream of a blood vessel of a patient, comprising:

a frame assembly made from a self-expanding material and having a plurality of longitudinally extending struts that move between a collapsed position and an expanded position; and

a filter element made from a filter membrane attached to the frame assembly, the filter element having a central region (page 40, lines 14-16; FIGS. 41 & 42; # 574) with an inlet opening and defining a storage reservoir for capturing embolic debris, the central region having a plurality of openings (page 40, lines 14-16; FIGS. 41 & 42; # 576) adapted to allow blood to flow therethrough but capture embolic debris larger than the size of the openings and contain the debris within the reservoir, and a filter edge (page 40, lines 16-20; FIGS. 41 & 42; # 572) integral with the central region and having an inlet opening, the filter edge having a pattern of alternating peak regions (page 40, lines 16-24; FIGS. 41 &42; #578) and valley regions(page 40, lines 16-24; FIGS. 41 & 42; # 580), each valley region having a particular depth (page 41, lines 5-16; FIG. 42) and each peak region has a particular height (page 41, lines 5-16; FIG. 42) and at least two peak regions having different heights.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Pursuant to the final Office Action dated September 15, 2008, the claims were rejected as follows:

GROUND I

Independent claims 94, 101, 105 and 114, along with their dependent claims, were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Broome patent (Exhibit 2) in view of the Gelbfish patent (Exhibit 3).

GROUND II

Dependent claims 115 and 116 were rejected under 35 U.S.C. § 103(a), however, these claims recite a specific frame assembly which is lacking in both the Broome patent and the Gelbfish patent.

VII. ARGUMENT

GROUND I

Claims 94-116 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Broome patent in view of the Gelbfish patent

The Examiner takes the position that the Gelbfish patent teaches an embolic filter with a sinusoidal configuration with valleys and peaks of different depths. Appellants strongly disagree with the Examiner characterization of the Gelbfish patent since this patent merely discloses a **frame wire component 156** formed in a zig-zag pattern (Figure 10), not a filter element **made from a filter membrane** as recited in **all** of the pending claims. The presently defined invention is specifically directed to the membrane portion of the embolic protection device which has a plurality of openings adapted to allow blood to flow therethrough but to capture embolic debris larger than the size of the openings and contain the debris within a

storage reservoir formed from the membrane. The membrane shown in the Gelbfish patent does not perform this function, but rather, simply acts as a **solid barrier** to direct blood flow and embolic material into a catheter used to capture the embolic material. A single, large opening, adjacent to this continuous web or film 166 and membrane 172, is used in the Gelbfish patent to direct blood flow into a debris removal instrument that is used to draw fluid and collected material out of the patient utilizing suction. This single opening of the Gelbfish membrane does not capture embolic debris larger than the size of the opening and contain the debris within a storage reservoir formed from the membrane, as is recited in all of the claims. If the embolic material was larger than this single opening, then the debris removal device of Gelbfish would simply get clogged.

The web or film 166 and membrane 172 of the Gelbfish device lack a plurality of perfusion openings. In fact, the Gelbfish patent actually teaches away from the use of perfusions openings in the web or film 166/ membrane 172 since the web or membrane is designed to enhance "the transmission of suction forces during a debris removal operation" (see column 11, lines 66-67 of the Gelbfish patent). Therefore, there are no perfusion openings in this "web or film 166" and "membrane 172" since this membrane must remain liquid impermeable in order to enhance the transmission of suction forces. Multiple openings in the Gelbfish membrane would inhibit the development of needed suction forces. Therefore, the use of a plurality of perfusion openings in the Gelbfish membrane would thwart the ability of the Gelbfish device to capture embolic material and create a suction that is needed to remove both the blood and embolic debris. Therefore, one skilled in the art would simply not look to the Gelbfish patent in solving the problems solved by the currently claimed invention since the Gelbfish membrane is used simply as a solid barrier to direct blood flow into another catheter that collects any embolic

material entrained inn the blood. Accordingly, the Gelbfish patent fails to disclose the filter element of the present claimed invention.

The position taken by the Examiner, namely, that "Gelbfish teaches an embolic filter with an edge of a sinusoidal configuration with valleys and peaks of different depths" only relates to the **wire frame** that supports the "web or film 166" or "membrane 172." The web 166 and membrane 172 in the Gelbfish patent are all shown as components having **a straight leading edge** and lack a plurality of with openings. Figures 9 and 11 of the Gelbfish patent are reproduced below:

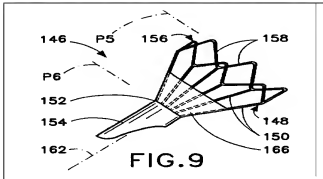

FIG.9

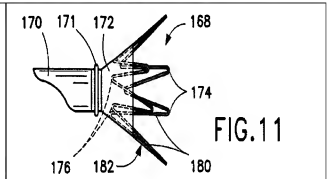

FIG.11

All of the webs or membranes disclosed in the Gelbfish patent have straight edges which are clearly shown in these figures above. Moreover, the Gelbfish does not teach that the web or membrane can be formed with the wire pattern shown in Figure 10. Rather, the Gelbfish patent states the following at column 11, lines 64-66:

> Filter body 148 is provided with a web or film 166 which renders the filter body liquid impermeable at least at its downstream side. Web or film 166 could be made long enough to cover or envelope prongs 150 and zig-zag element 156.

Therefore, the Gelbfish patent does not teach a filter membrane or web that has an edge configured in the shape shown in Figure 10. Rather, the web or

membrane is simply extended upward with a linear edge as shown to cover the frame wire as is depicted in Figure 11 above.

Appellant submit that the Broome patent fails to disclose the structure of the pending claims as has been admitted by the Examiner in previous Office Actions. Appellant believes that the Examiner has simply used the claims as a roadmap in an attempt to reconstruct the presently claimed invention. The Gelbfish patent clearly fails to teach the use of a filter membrane that includes a filter edge having peaks and valleys of varying heights and depths. While it may use a wire edge in its support structure to avoid having the support frame enter into the coupling sleeve 154 at the same time, it is noted that the entire filter web 116 is drawn **proximally into the coupling sleeve 154** at the same time. Figures 3A and 3D of the Gelbfish patent show how a rod or wire 42 is used to retract the support frame and filter web **proximally into the tubular member or sleeve 26/154**. Therefore, there is no need for the filter web/membrane used in the Gelbfish patent to include an edge with a staggered sinusoidal pattern. Accordingly, the Gelbfish patent discloses only a filter web with a straight leading edge. Moreover, the web/membrane of the Gelbfish device is simply used as a solid, but flexible**, funnel** for directing debris into the lumen of a catheter. Given this function, along with Gelbfish's teaching of the use of a straight edge web/membrane, there appears to be no reasonable reason why one skilled in the art would combine the Daniel patent with the Gelbfish patent in the first place, unless of course, one was simply attempting to reconstruct the device using the claims as a roadmap. These are the reasons why Appellant believes that the Examiner has simply used the claims to piece together unrelated devices in order to reject the pending claims.

GROUND II

Claim 115 requires each strut of the frame assembly to have a proximal end and a distal end, the proximal ends of the struts being attached to a proximal collar and the distal ends being attached to a distal collar. Appellant believe that this particular structure is not shown in the Broome patent or Gelbfish patent. The Examiner has taken the position that the element referred to as the mouth 28 of the frame 24 in the Broome patent constitutes a collar. Claim 116 requires each peak region of the filter element to be attached to a **strut** of the frame assembly. Claims 115 and 116 are directed to the embodiment disclosed in FIG. 41. Since the Examiner has taken the position that the mouth 28 constitutes one of the **collars**, the mouth 28 cannot constitute a strut of the frame assembly. The Broome patent clearly shows the filter element attached to the mouth 28 or collar, as the Examiner has interpreted the Broome patent. Therefore, the filter 22 of the Broome patent would not be considered attached to a strut of the frame assembly, as recited in claim 116, but rather, is attached to this "collar 28." The Examiner apparently has taken the position that the filter element is **indirectly** attached to the struts since the collar 28 is attached to the struts. However, Appellant believes that the Examiner's position is not a reasonable interpretation of the Broome patent. The Gelbfish patent also lacks the particular structure recited in claims 115 and 116. Accordingly, the combination of the Gelbfish patent with the Broome patent fails to disclose the particular structure recited in claim 116.

VIII. CLAIM APPENDIX

See Exhibit 1.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

NONE

XI. CONCLUSION

Appellant submits that there is no believes that the pending claims can be passed to issue as these claims were improperly rejected by the Examiner.

The filing fee of $510.00 was paid on May 21, 2009 with the Pre-Appeal brief. The Commissioner is hereby authorized, however, to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 06-2425.

Respectfully submitted,

FULWIDER PATTON LLP

/Thomas H. Majcher/
Thomas H. Majcher, Reg. No. 31,119

EXHIBIT 1

EXHIBIT 1 - CLAIMS

1-93. (Canceled)

94. A filter element for capturing embolic debris released into the bloodstream of a blood vessel of a patient, comprising:

a central region having an inlet opening and defining a storage reservoir for capturing embolic debris, the central region having a plurality of openings adapted to allow blood to flow therethrough but capture embolic debris larger than the size of the openings and contain the debris within the reservoir; and

a filter edge integral with the central region and having an inlet opening, the filter element being adapted to move from an expanded position to a collapsed position by sliding a restraining sheath initially over the filter edge and thereafter over the central region to move at least a portion of the filter element into the restraining sheath, the filter edge having a pattern of alternating peak regions and valley regions which prevent the filter edge from entering into the restraining sheath all at one time, wherein each valley region has a particular depth and each peak region has a particular height and at least two peak regions have different heights and the central region and filter edge are made from a filter membrane.

95. The filter element of claim 94, wherein the filter edge has a sinusoidal configuration which includes peak and valley regions.

96. The filter element of claim 94, wherein the peak regions are attachable to struts of a strut assembly.

97. The filter element of claim 94, wherein the filter edge includes at least a first valley region and a second valley region, the depth of the first valley region being smaller than the depth of the second valley region.

98. The filter element of claim 94, wherein the filter edge includes at least a first valley region and a second valley region, the depth of the first valley region being the same as the depth of the second valley region.

99. The filter element of claim 94, wherein the filter edge includes at least a first peak region, a second peak region and a third peak region, the height of the first peak region being less than the height of the second peak region and the height of the second peak region being less than the height of the third peak region.

100. The filter element of claim 99, wherein the filter edge includes at least a first valley region and a second valley region, the depth of the first valley region being smaller than the depth of the second valley region.

101. A filter element for capturing embolic debris released into a body vessel, comprising:

a central region having an inlet opening and defining a storage reservoir for capturing embolic debris, the central region having a plurality of openings; and

a filter edge integral with the central region and having an inlet opening, the filter element being adapted to move from an expanded position to a collapsed position by sliding a restraining sheath initially over the filter edge and thereafter over the central region to move at least a portion of the filter element into the restraining sheath, the filter edge having a pattern of alternating peak regions and valley regions, wherein each valley region has a particular depth and each peak region has a particular height, at least two peak region having different heights and each valley region has a round configuration which reduces stress concentration at the valley region and the central region and filter edge are made from a filter membrane.

102. The filter element of claim 101, wherein each valley region has a semi-circular shape.

103. The filter element of claim 101, wherein each peak region has a round configuration.

104. The filter element of claim 101, wherein each valley region has a different depth.

105. A filter element for capturing embolic debris released into a body vessel, comprising:

a central region having an inlet opening and defining a storage reservoir for capturing embolic debris, the central region having a plurality of openings; and

a filter edge integral with the central region and having an inlet opening, the filter element being adapted to move from an expanded position to a collapsed position by initially drawing the filter edge into the catheter and thereafter the central region to move at least a portion of the filter element into the catheter, the filter edge having a sinusoidal pattern of alternating peak regions and valley regions, wherein the filter element can be drawn into the catheter and the valley regions are staggered so that no two valley regions enter the catheter at the same time and the central region and filter edge are made from a filter membrane.

106. The filter element of claim 105, wherein the peak regions are staggered so that no two peak regions enter the catheter at the same time

107. The filter element of claim 106, wherein each of the peak regions and valley regions have a round configuration.

108. The filter element of claim 94, wherein each valley region has a semi-circular shape.

109. The filter element of claim 94, wherein each peak region has a round configuration.

110. The filter element of claim 105, wherein each valley region has a semi-circular shape.

111. The filter element of claim 105, wherein each peak region has a round configuration.

112. The filter element of claim 94, further including a strut assembly having a plurality of radially expandable struts which extend from a proximal end of the strut assembly to a distal end of the strut assembly, wherein each peak region of the filter edge is attached to one of the plurality of radially expandable struts.

113. The filter element of claim 101, further including a strut assembly having a plurality of radially expandable struts which extend from a proximal end of the strut assembly to

a distal end of the strut assembly, wherein each peak region of the filter edge is attached to one of the plurality of radially expandable struts.

114. A filter assembly for capturing embolic debris released into the bloodstream of a blood vessel of a patient, comprising:

a frame assembly made from a self-expanding material and having a plurality of longitudinally extending struts that move between a collapsed position and an expanded position; and

a filter element made from a filter membrane attached to the frame assembly, the filter element having a central region with an inlet opening and defining a storage reservoir for capturing embolic debris, the central region having a plurality of openings adapted to allow blood to flow therethrough but capture embolic debris larger than the size of the openings and contain the debris within the reservoir, and a filter edge integral with the central region and having an inlet opening, the filter edge having a pattern of alternating peak regions and valley regions, each valley region having a particular depth and each peak region has a particular height and at least two peak regions having different heights.

115. The filter element of claim 114, wherein each strut has a proximal end and a distal end, the proximal ends of the struts being attached to a proximal collar and the distal ends being attached to a distal collar.

116. The filter element of claim 115, wherein each peak region is attached to a strut of the frame assembly.

EXHIBIT 2

United States Patent [19]

Canup

[11] **4,320,735**

[45] **Mar. 23, 1982**

[54] **HIGH-FREQUENCY CONTINUOUS-WAVE IGNITION SYSTEM**

[75] Inventor: **Robert E. Canup**, Poughkeepsie, N.Y.

[73] Assignee: **Texaco, Inc.**, White Plains, N.Y.

[21] Appl. No.: **152,946**

[22] Filed: **May 23, 1980**

[51] **Int. Cl.**[3] **F02P 3/02**; H03K 17/72; F02P 1/00

[52] **U.S. Cl.** ..... **123/606**; 123/607; 123/651; 123/652; 307/252 C; 307/305; 315/209 SC; 331/111

[58] **Field of Search** ..... 123/651, 652, 605, 606, 123/607, 618, 619, 630, 648; 307/252 C, 305; 315/209 SC; 331/111

[56] **References Cited**

U.S. PATENT DOCUMENTS

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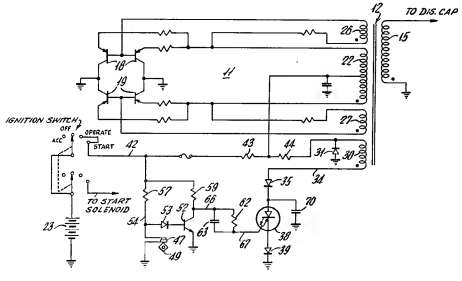
3,961,613	6/1977	Canup	123/606
4,016,433	4/1977	Brooks	123/651
4,084,566	4/1978	Weiler	123/651
4,097,770	6/1978	Fisher	123/605
4,109,632	8/1978	Brooks	123/619

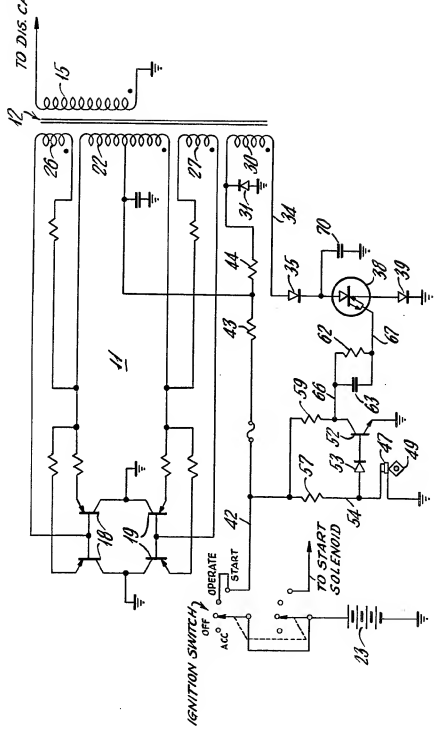
Primary Examiner—Raymond A. Nelli
Attorney, Agent, or Firm—Carl G. Ries; Robert A. Kulason; Henry C. Dearborn

[57] **ABSTRACT**

An ignition system that develops continuous-wave high-frequency spark signals. It employs a square wave oscillator which uses a unitary magnetic circuit and includes a control winding that acts to start and stop the oscillator. The control winding has a gate-turn-off type silicon controlled rectifier in circuit with it, which provides superior control action.

3 Claims, 1 Drawing Figure




TO DIS. CAP
IGNITION SWITCH
OFF
ACC
OPERATE
START
TO START SOLENOID

HIGH-FREQUENCY CONTINUOUS-WAVE IGNITION SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention concerns ignition systems for internal combustion engines, in general. More specifically, it relates to an improvement for a particular type of ignition system that employs high-frequency continuous-wave spark energy. The improvement relates to an aspect of the control for such an ignition system. The control involves the use of a control winding for starting and stopping the oscillation of a square wave oscillator, which produces the indicated high-frequency continuous-wave spark energy.

2. Description of the Prior Art

A highly successful ignition system has been developed which employs a single transformer, and makes use of a high-frequency continuous-wave signal that is delivered to the spark plugs. It has a controlled duration that may be determined in various manners, and it ensures a superior spark signal at each of the cylinders. Such an ignition system is exemplified by the U.S. Pat. No. 3,961,613, issued June 8, 1976. Also, there are additional patents that show and describe the same basic type of superior ignition system that is of concern here. However, it has been found that because the control winding of those ignition systems was being controlled by a transistor acting as an electronic switch, the current and/or power requirements created the need for a very expensive transistor in order to have the necessary power rating.

The aforementioned electronic control of the indicated type of ignition system made use of what may be described as a series pass transistor. It acted in series with a control winding on the above indicated single transformer which was a high voltage power type that delivered the spark signals. During the off state of the high-frequency continuous-wave spark signals, a DC current flowed through the control winding and the series pass transistor to ground. Then when a spark signal was required a high voltage oscillator was turned on by stopping the flow of the DC current through the control winding. The consequent decaying magnetic flux was sufficient to start the oscillator. Stopping the DC current flow was accomplished by turning off the series pass transistor. The oscillator would continue to run as long as the series pass transistor was off, and it would develop an AC voltage in the control winding. But, when the series pass transistor was off no current flowed in the control winding, either AC or DC.

At the end of a spark signal the oscillator would be stopped by turning on the series pass transistor. That would allow both the DC current from the battery and AC current from the oscillator action, to flow. The AC current flow would be sufficient to overload the oscillator and cause the oscillation to cease.

In a system such as just described, the starting of the oscillator reliably, required a certain amount of DC flux to be present in the transformer core when the circuit was broken. That flux is proportional to the current times the number of turns in the control winding. If the current was large, then the current drain on the battery was at a high level during the times when the oscillator was not oscillating. On the other hand, if the number of turns in the control winding was large, then a large AC voltage would be generated in this winding while the oscillator was running. Such voltage would appear at the collector of the series pass transistor. And if that voltage was too large, the breakdown voltage of the transistor would be exceeded and the transistor would fail.

In the foregoing type system, in order to stop the oscillator, it was necessary to draw enough power into the control winding circuit to reduce the loop gain of the oscillator to less than a gain of one. That required the control winding to be essentially short circuited. And since there was a high voltage present at the collector of the series pass transistor when it was turned on, a very large current would flow momentarily. Also, if the series pass transistor was capable of handling the large current surge, the oscillator would shut down. However, if the oscillator did not shut down on the first current surge, the oscillator would continue to run and cause the transistor to draw repetitive high surges of current which would soon destroy it.

Thus, it has been found that a series pass transistor in the foregoing system had to be capable of withstanding about 300–400 volts on the collector while off, and to handle current surges of about 10–50 amperes. So a transistor meeting such requirements was very expensive.

Consequently, it is an object of this invention to improve a particular ignition system that has a superior AC spark signal.

There is a U.S. Pat. to Fisher No. 4,097,770 issued June 27, 1978, that discloses a triggering circuit for a silicon controlled rectifier. However, it is applied to a capacitor discharge type of automobile ignition system, and consequently is not relevant to the applicant's invention.

SUMMARY OF THE INVENTION

The invention concerns an improvement that is in combination with a high-frequency continuous-wave ignition system for an internal combustion engine. The said system includes a square wave oscillator employing a unitary magnetic circuit and it includes a control winding for starting and stopping said high-frequency continuous-wave energy to generate a continuous AC spark whenever said oscillator is oscillating. The said system also includes means for timing said AC spark duration intervals, relative to said engine. The improvement comprises high current means for applying a low impedance path to said control winding concurrently with DC current therethrough between each said spark duration interval.

Again briefly, the invention relates to an improvement that is in combination with a high-frequency continuous-wave ignition system for an internal combustion engine. The said system includes a square wave oscillator employing a unitary magnetic circuit and including a control winding for starting and stopping said high-frequency continuous-wave energy, to generate a continuous AC spark whenever said oscillator is oscillating. The said system also includes means for timing said AC spark duration intervals relative to said engine. The improvement comprises a gate turn-off type silicon controlled rectifier for applying a low impedance path to said control winding concurrently with a DC current therethrough, between each said spark duration interval. And, said spark duration timing means comprises engine timed means for controlling the conductive state of a transistor. There is a resistor and capacitor con-

nected in parallel with one end connected to the gate of said gate controlled rectifier, and the other end connected to said transistor for grounding that end when said transistor is conducting. It also comprises circuit means for connecting said engine timed means to the base of said transistor.

BRIEF DESCRIPTION OF THE DRAWING

The foregoing and other objects and benefits of the invention will be more fully set forth below in connection with the best mode contemplated by the inventor of carrying out the invention, and in connection with which there are illustrations provided in the drawing, wherein:

The FIGURE of drawings is a schematic circuit diagram, illustrating an ignition system with the control element according to this invention shown therein.

DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to the FIGURE of drawings, it is to be noted that there is illustrated a high-frequency continuous-wave ignition system which is a known type. It is substantially like the ignition systems shown and described in a number of issued U.S. patents, e.g. U.S. Pat. No. 3,961,613, issued June 8, 1976. Thus, the ignition system illustrated includes a relatively high-frequency square wave oscillator **11**. It employs a unitary magnetic circuit which includes a transformer **12** that has an output winding **15**. The latter delivers AC spark signals to the spark plugs (not shown) of an internal combustion engine, by having one end of the winding **15** connected to a distributor (not shown) as indicated by the caption "To Dis.Cap". The other end of the winding **15** is grounded, as indicated.

The oscillator **11** includes two pairs of transistors **18** and **19** which are connected in the oscillator circuit with the collector electrodes grounded. The emitter electrodes are connected to the ends of a center tapped winding **22**. The center tap of winding **22** is connected to a power source by the indicated circuit connections. These connections go through an ignition switch (see the caption) which connects a source of power, e.g. a battery **23** to the oscillator **11** when the ignition switch is turned on. The oscillator **11** includes feedback windings **26** and **27** that have one end of each connected to the base electrodes of the transistors **18** and **19**, respectively.

The oscillator **11** is part of a superior ignition spark signal generating system like the known type indicated above. It employs a control winding **30** that acts to start and stop the oscillator **11**. Such control is carried out in the manner that is clearly described in the various earlier patents mentioned above. The action involves keeping the oscillator non-oscillating during the times when no spark signal is desired. That is done by having an AC short circuit on the control winding **30**. Such short circuit includes a diode **31** that has one side grounded and is connected to one end of the winding **30**, while the other end of winding **30** goes via a circuit connection **34** to another diode **35** and then via an electronic switch element **38** to another diode **39** that has the other side thereof grounded.

At the same time, there is a DC current which flows through the control winding **30** during the non-oscillating time of oscillator **11**. This DC is employed to act on the magnetic circuit of the transformer **12** for starting the oscillator **11** instantaneously at the desired time. This is accomplished by cutting off the DC current flow.

The foregoing current flows over a path that leads from battery **23** and goes over a circuit connection **42**. Then it goes via resistors **43** and **44** to one end of winding **30**, and then from the other end via the circuit connection **34** and the diode **35** plus the electronic switch element **38** and the other diode **39** to ground. From the ground connection, the circuit is completed via ground to the other end of the battery **23**.

Heretofore, a known type ignition system in accordance with the description above, employed a transistor to act as an electronic switch element in circuit with the control winding to start and stop the oscillator. However, it was found that the current and voltage requirements of such switch were such that it was difficult to have the system work properly. Thus, the aforementioned requirements of high voltage and/or high current required a very expensive transistor, and even so it was subject to short life or breakdown.

However, it has been discovered that a silicon controlled rectifier type switch may be employed, and it will act to overcome the prior difficulties. Such a switch is known as a gate-turn-off type of silicon controlled rectifier.

The spark duration timing, i.e. the control of the oscillation of oscillator **11**, is determined by having an engine timed means to control the conductive and non-conductive state of the electronic switch element **38**. Thus, while different type of engine timed means may be employed to develop the required control signals, the system illustrated employs a pair of breaker points **47** that are actuated by an engine driven cam **49**.

In the illustrated system, the breaker points **47** are connected into the control circuit of a transistor **52**. Also, there is a diode **53** connected between a circuit connection **54** and the base electrode of transistor **52**. The circuit connection **54** goes from the breaker points **47** to one end of a resistor **57**. The other end of resistor **57** is connected into the circuit connection **42** that leads to the battery **23**.

The transistor **52** has the collector electrode thereof connected via a resistor **59** to the battery **23** via the circuit connection **42**, while the emitter electrode of transistor **52** is connected to ground as indicated. There is a resistor **62** and a capacitor **63** that are connected in parallel. One end of that pair of elements is connected to the collector electrode of transistor **52** via a circuit connection **66**. And, the other end of the parallel resistor **62** and capacitor **63**, is connected to the gate of the electronic switch element **38**, which is a gate-turn-off type of silicon controlled rectifier.

OPERATION

The system operation is such that during the time when no spark signal is required from the output winding **15** of transformer **12**, the electronic switch element **38**, i.e. the gate-turn-off type of silicon controlled rectifier is conducting and the control winding **30** is maintained with a short circuit for AC signals as well as having a DC current flow therethrough. Under these conditions the transistor **52** is off (non-conductive) and there is current flow from the battery **23** via the circuit connection **42** and resistors **59** and **62** into the gate of the silicon controlled rectifier **38** via the circuit connection **67**. Such current flow is sufficient to have the gate-turn-off switch element **38** regenerative, and consequently it will be turned on so that the indicated condi-

tions will obtain, i.e. having DC current flow from the battery through the winding **30** and maintaining an AC short circuit via the turned-on silicon controlled rectifier **38**.

When a spark is required, the transistor **52** is turned on (made conducting) by having the breaker points **47** open. This applies high voltage to the base electrode of transistor **52** via the diode **53**. Turning on of the transistor **52** will pull the voltage at the junction between resistor **59** and resistor **62** (i.e. at circuit connection **66**) essentially to ground or zero. Then, since the cathode of the silicon controlled rectifier **38** is approximately 0.7 volts above ground (which is caused by the forward voltage drop across the diode **39**), the gate of the element **38** is pulled negative which helps turn off the gate controlled rectifier **38**. In addition, when the transistor **52** is turned on, the capacitor **63** discharges from a plus voltage to ground. This discharges the left side of the capacitor **63**, i.e. the side connected to circuit connection **66**, which causes a negative pulse to appear on the other side and thus at the gate of the gate-turn-on silicon controlled rectifier **38**, via the circuit connection **67**. The combination of the negative pulse on the circuit connection **67** and the forward bias on the diode **39** will turn off the control current flowing through the gate of the silicon controlled rectifier **38**.

Turning off the current flow through control winding **30** starts the oscillator **11** in the manner known for this type of ignition system, that is already indicated above. The negative portions of the AC voltage which exists in the control winding **30** will be prevented from reaching the anode of the gate-turn-off silicon control rectifier **38** by the diode **35**, so that only a positive voltage will appear at the anode. There is a capacitor **70** which filters the AC ripple so that essentially pure DC is present at the anode of the silicon controlled rectifier **38** while the oscillator is running.

When it is desired to stop the oscillator **11**, the transistor **52** is turned off which causes the voltage at the connection **66** to go positive, and a positive pulse is transmitted to the gate of the electronic switch **38** via the circuit connection **67**. Such pulse is caused by the charging of the capacitor **63**. At the same time, a steady state DC is applied through the resistor **62**, and the combination provides sufficient forward bias to turn the gate-turn-on silicon controlled rectifier on. The current then will flow from the control winding **30** through the diode **35**, the electronic switch **38**, the diode **39** and to ground from there through the diode **31** back to the control winding **30**. This AC short circuit current flow will overload and stop the oscillator **11**. Also, the DC current will be established through the resistors **44** and **43** through the control winding **30**, which then sets the magnetic flux in the core **12** of the transformer so as to be ready for the next cycle of spark signals when the oscillator **11** is turned on again.

While a particular embodiment of the invention has been described above in considerable detail in accordance with the applicable statutes, this is not to be taken as in any way limiting the invention but merely as being descriptive thereof.

I claim:

1. In combination with a high-frequency continuous-wave ignition system for an internal combustion engine, said system including a square wave oscillator employing a unitary magnetic circuit and including a control winding for starting and stopping said high-frequency continuous-wave energy to generate a continuous AC spark whenever said oscillator is oscillating, said system also including means for timing said AC spark duration intervals relative to said engine, the improvement comprising

a gate turn off type silicon controlled rectifier for applying a low impedance path to said control winding concurrently with a DC current therethrough between each said spark duration interval, and

said spark duration timing means comprising engine timed means for controlling the conductive state of a transistor,

a resistor and capacitor connected in parallel with one end connected to the gate of said gate controlled rectifier and the other end connected to said transistor for grounding that end when said transistor is conducting, and

circuit means for connecting said engine timed means to the base of said transistor.

2. In combination with a high-frequency continuous-wave ignition system for an internal combustion engine, said system including a square wave oscillator employing a unitary magnetic circuit and including a control winding for starting and stopping said high-frequency continuous-wave energy to generate a continuous AC spark whenever said oscillator is oscillating, said system also including means for timing said AC spark duration intervals relative to said engine, the improvement comprising

a gate turn off type silicon controlled rectifier for applying a low impedance path to said control winding concurrently with a DC current therethrough between each said spark duration interval,

said spark duration timing means comprising engine timed means for controlling the conductive state of a transistor, and

a resistor and capacitor connected between said transistor and the gate of said gate controlled rectifier,

said resistor and capacitor being connected in parallel with one end connected to said gate.

3. The invention according to claim **2**, wherein

said spark duration timing means also comprises circuit means for connecting said engine timed means to the base of said transistor,

said transistor being connected to the other end of said parallel resistor and capacitor to ground same when said transistor is conducting.

* * * * *

EXHIBIT 3

US005800457A

United States Patent [19]

Gelbfish

[11] Patent Number: 5,800,457

[45] Date of Patent: Sep. 1, 1998

[54] **INTRAVASCULAR FILTER AND ASSOCIATED METHODOLOGY**

[76] Inventor: **Gary A. Gelbfish**, 2502 Avenue I, Brooklyn, N.Y. 11210

[21] Appl. No.: **811,919**

[22] Filed: **Mar. 5, 1997**

[51] Int. Cl.[6] **A61B 17/22**

[52] U.S. Cl. **606/200**

[58] **Field of Search** 606/200, 127

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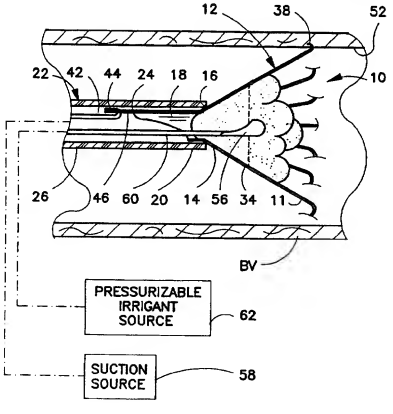
Primary Examiner—Michael H. Thaler

Attorney, Agent, or Firm—R. Neil Sudol; Henry D. Coleman

[57] **ABSTRACT**

An intravascularly deployable device in the nature of a filter for collecting intravascular debris includes a filter or collector body expandable from a collapsed insertion configuration to an expanded use configuration. The use configuration of the filter body tapers down from a maximum cross-sectional area to a minimal cross-sectional area at a downstream end of the filter body. The filter body is provided at the downstream end with an access port so that the instrument can traverse the access port to remove debris from the filter body after disposition of the intravascularly deployable device inside a blood vessel of a patient. The access port takes the form of a sleeve or chimney which is beveled to taper down from a maximal transverse dimension at an upstream end to a minimal transverse dimension at a downstream end. The beveled or tapered sleeve is especially useful in locating or guiding the distal end of the debris removal instrument onto the downstream end of the filter body during a shifting of the instrument in the upstream direction towards the filter body.

31 Claims, 4 Drawing Sheets



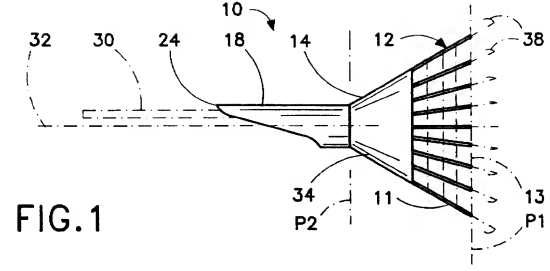


FIG.1

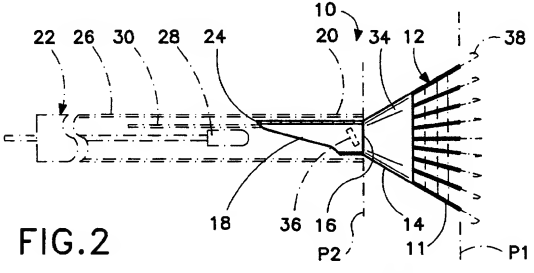


FIG.2

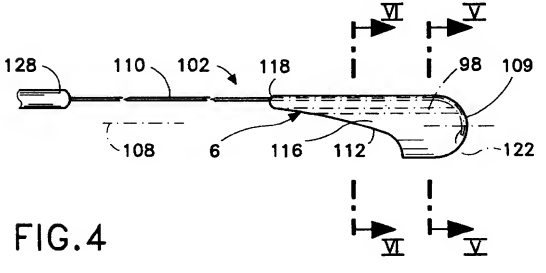


FIG.4

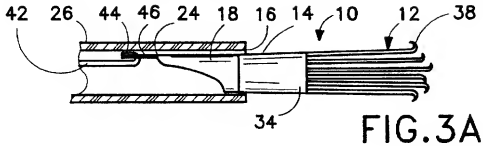


FIG.3A

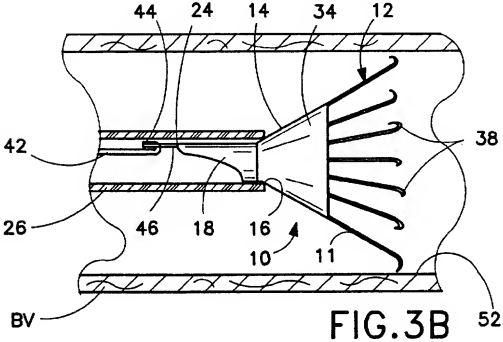


FIG.3B

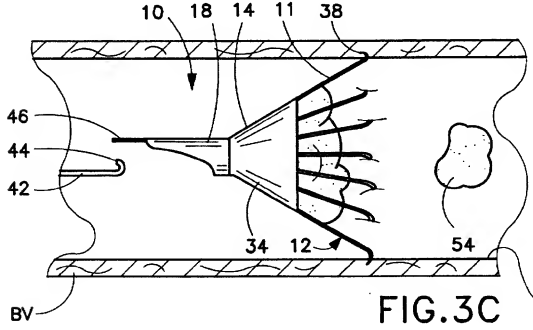


FIG.3C

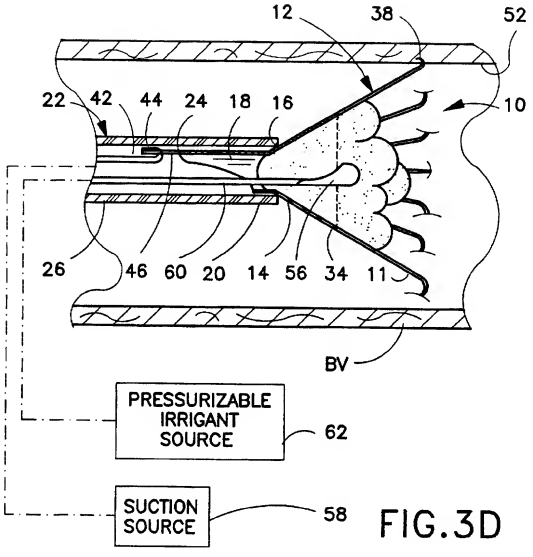


FIG.3D

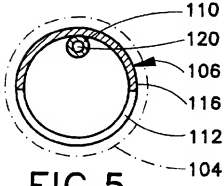


FIG.5

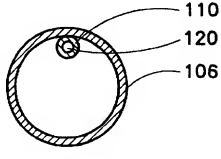


FIG.6

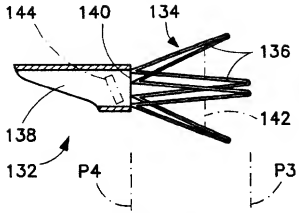


FIG.7

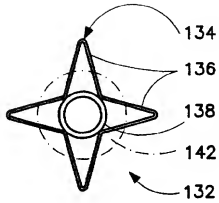


FIG.8

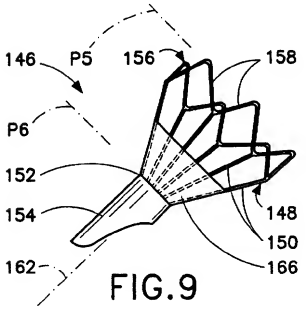


FIG.9

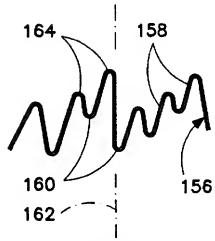


FIG.10

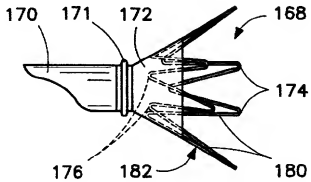


FIG.11

INTRAVASCULAR FILTER AND ASSOCIATED METHODOLOGY

BACKGROUND OF THE INVENTION

This invention relates to an intravascular filter. This invention also relates to an associated minimally invasive method for collecting and removing vascular debris.

Vascular filters are in common use in the vascular system. They are frequently used for patients with clot in the large veins of the lower portions of the body. This condition is known as DVT, which is an acronym for "Deep Venous Thrombosis." In these patients with DVT, there exists the constant risk of clot breaking off and traveling via the vena cava to the heart and lungs. This process is known as pulmonary embolization and is frequently fatal, because the embolized clot interferes with the life-sustaining pumping mechanism of the heart.

These vascular filters are designed in various conical and web-like configurations. Multiple designs have been described in the medical and patent literature. These include the most common filter used in clinical medicine today, described in U.S. Pat. No. 3,952,747 to Kimmell, U.S. Pat. No. 4,643,184 to Mobin-Uddin, U.S. Pat. No. 425,908 to Simon, U.S. Pat. No. 4,688,553 to Metals and others. The vascular filters of these prior art patents all function to catch clots circulating in the vascular system. Once entrapped by a vascular filter, clots are held in the vascular system at the location of the filter, which is most commonly placed in the inferior vena cava at approximately the level of the navel. Most filters are conical so as to direct entrapped clot to the central portion of the filter, while leaving the periphery of the filter and vessel open for blood flow. Thus, if only a small volume of clot has been trapped, blood may continue to flow across the filter and no major hemodynamic abnormalities arise. Clots at the level of the inferior vena cava are less damaging than clot in the heart or lungs and are usually not fatal. In most cases, the filters are inserted and left in place permanently. They often have specialized barbs that are designed to keep the filters in place and prevent their unintended movement.

Another proposed utility for vascular filters is disclosed in the patent literature, but has found limited clinical applicability thus far. Pursuant to this utility, a temporary filter is placed downstream from a vascular intervention such as an atherectomy or mechanical thrombectomy procedure. It is contemplated that the debris generated from the invasive vascular procedure is trapped in the filter. The filter is then withdrawn from the body with the enclosed debris.

The current state of the art in filter technology has a major deficiency related to the inability or significant difficulty in extracting the entrapped clots from the body. The extent of this difficulty depends on filter design and function.

A) For those filters described above that are permanently placed, there exists no apparent method for removal of entrapped clot. To the contrary, the current designs, which utilize a web-like configuration of wires that function to capture or collect clot, would also seriously hamper any effort to remove clot. This accumulation of clot by the filter may lead to complete obstruction and thrombosis of the inferior vena cava, distal to the filter, if an extensive amount of clot has been caught by the filter. This condition may lead to significant clinical symptoms, such as swelling edema, and infection of the lower portions of the body, related to poor venous return, since this major venous blood vessel is occluded.

Notwithstanding these side effects, complete occlusion of the inferior vena cava at the level of the filter usually

indicates a successful performance of the filter, since without the filter in place, this large volume of clot would have almost certainly have led to significant pulmonary embolism and death. Yet while occlusion of the inferior vena cava may be the lesser of two evils, a mechanism to remove the obstructing clot at will, after it has been trapped by the filter yet without the need to extract the filter, would be most beneficial. Removing the vascular debris collected in the filter would restore the lumen to the previously occluded blood vessel and concomitantly restore blood flow.

B) Where the filters are intended for temporary use in trapping debris downstream from a vascular intervention, as described in U.S. Pat. No. 4,873,978 to Ginsburg, the filters are designed to be removed from the body once some clot or debris has been trapped. This is the proposed mechanism of debris removal and is the only mechanism possible considering the present structural configurations of such filters. The requirement to repetitively remove the filters, clean the debris and then reinsert the filters into the body, makes them unsuitable for processing significant amounts of clot or other debris.

Besides traditional filters, multiple other devices have been described, whose primary function is to facilitate the removal of clot from the vascular system. In general, the devices use an active method to seek out clot in the vascular system so that the clot may be removed. Various energy sources are used for clot modification and extraction. This active approach is in contrast to the approach of vascular filters that are designed to passively wait until embolized clot is trapped. Two known clot extraction devices utilize a hybrid structure in that they share a similar mechanism to the above described passive filters, notably a radially expanding tip. U.S. Pat. No. 5,011,488 to Ginsburg discloses a tubular structure with a fan-like distal end that is self-expanding in the vasculature when pushed out of an outer constricting sheath. U.S. Pat. No. 5,102,415 to Guenther describes a device with a similar function but having a novel cross-wire mesh-like filtering mechanism. Both these devices, however, consist of concentric tubular structures each of which extends along the entire length of the outer device and has a proximal end terminating at a point external to the body. The distal, intravascular, working end of the inner tube is concentrically fused to the radially expanding fan shaped end of the tube and is one continuous functional structure. This desiga, disclosed by both these patents, precludes deployment of the disclosed devices as permanent intravascular filters and is clearly not proposed for this use. In addition, because of their concentric tubular design, these filter-like devices have increased bulk and complexity. These factors will no doubt decrease the efficiency of clot removal since the concentric arrangement causes the clot extraction lumen to be necessarily narrowed. This is probably the reason why both U.S. Pat. No. 5,011,488 and U.S. Pat. No. 5,102,415 teach a method of first entrapping clot and then removing the entire inner tube and attached filter device together with the entrapped clot. This is similar to the mechanism proposed in U.S. Pat. No. 4,873,978 to Ginsburg using a filter of a different configuration. As mentioned, this method of use is not applicable to large volumes of clot.

Thus, the field of radially expanding, filter-like devices presently has no mechanism, actual or proposed, for removing clot from an intravenous filter other than by removing the filter from the body. This is true both for those radially expanding filter-like devices that are designed primarily for clot entrapment and those designed primarily for clot extraction. This is regardless of whether the devices are intended for permanent or temporary placement.

OBJECTS OF THE INVENTION

An object of the present invention is to provide an improved intravascular filter device.

A more particular object of the present invention is to provide such a filter device which enables or facilitates the removal of intravascular debris collected by the filter device.

An even more specific and especially important object of the present invention is to provide such a filter device which is compatible with clot removal, that is, wherein collected intravascular debris can be removed while the filter remains in place in a blood vessel of a patient.

Another object of the present invention is to provide a permanently or, alternatively, a temporarily implanted filter device of this kind.

A further object of the present invention is to provide an improved method of removing intravascular debris such as clots from a patient.

These and other objects of the present invention will be apparent from the descriptions and drawings herein.

BRIEF DESCRIPTION

An intravascularly deployable device in accordance with the present invention basically comprises an expandable filter or collector which is provided with an access port enabling the removal of collected debris from the collector while the collector is in place in the vascular system of a patient. The access port is designed to facilitate a temporarily coupling of a debris removal instrument to the collector to enable the removal of collected vascular debris via the access port.

More specifically, an intravascularly deployable device in the nature of a filter for collecting intravascular debris comprises, in accordance with the present invention, a filter or collector body expandable from a collapsed insertion configuration to an expanded use configuration. The use configuration of the filter body tapers down from a maximum cross-sectional area to a minimal cross-sectional area at a downstream end of the filter body. The filter body is provided at the downstream end with an access port which functions as a coupling element for cooperating with a distal end of an elongate debris removal instrument to removably connect the instrument to the filter body so that the instrument can traverse the access port to remove debris from the filter body after disposition of the intravascularly deployable device inside a blood vessel of a patient.

In a particular embodiment of the invention, the access port or coupling element takes the form of a sleeve which is beveled to taper down from a maximal transverse dimension at an upstream end to a minimal transverse dimension at a downstream end. The beveled or tapered sleeve is especially useful in locating or guiding the distal end of the debris removal instrument onto or into the downstream end of the filter body during a shifting of the instrument in the upstream direction towards the filter body. More specifically, where the debris removal instrument has a tubular outer member, the tubular member is slid over or into the sleeve. At the maximal cross-sectional area of the sleeve, the beveled sleeve and the tubular member are snugly fit together, one inside the other. A cutting element coupled with the tubular member (e.g., partially disposed therein) obtains access to the filter body via the access port thereof.

In a particular feature of the present invention, the cutting element is slidable relative to the tubular member. Accordingly, the cutting element is longitudinally shiftable in a distal direction through the tubular member and into the filter body through the access port thereof. It is to be understood that other kinds of cutting elements are possibly utilizable with a filter device in accordance with the present invention. For example, a rotary cutting element which is or is not longitudinally shiftable relative to an outer sheath member may be used.

In accordance with another feature of the present invention, a connector is disposed on the sleeve at the downstream end thereof for enabling a connection of a rod to the sleeve so that the rod extends substantially parallel to a longitudinal axis of the sleeve, eccentrically relative to the sleeve. The rod may be used to place the filter device inside the blood vessel of the patient. After the deployment of the filter device, the rod is disconnected from the sleeve and removed from the patient. Subsequently, the rod may be used as a guide wire for the debris removal instrument. The rod is reinserted into the blood vessel and linked to the filter device via the connector at the downstream end of the sleeve. The tubular member of the debris removal instrument is then inserted into the blood vessel over the rod.

In accordance with a further feature of the present invention, the filter body is liquid impermeable at least in a region about the access port. This impermeability is provided by a web or film disposed on the filter body. The film may extend partially or entirely the length of the filter body or even beyond the filter body. Moreover, the film may be located over the filter body or within the filter body or, alternatively, where the filter body has longitudinal prongs, these prongs may be embedded in the film. Where the debris removal instrument uses applied suction, the web or film on the filter body facilitates removal of debris collected in the filter body by enhancing the suction action and decreasing associated blood loss.

It is to be noted that the chimney of sleeve must be appropriately and minimally sized so that dangerous clots do not unintentionally and spontaneously pass through the filter device. Alternatively, the filter body may have a movable flap at the apex of the that is normally in the closed position and is only opened when a clot removal procedure is undertaken.

Where the filter body is intended to remain inside the patient, the filter body is provided at a location spaced from the access port with barbs or other means for fixing the body to the wall of the blood vessel. However, a filter device in accordance with the present invention may be deployed only temporarily in the vascular system of a patient, for example, to collect debris generated during a vascular operation upstream of the filter deployment position. In this case, the filter device may include a rod permanently connected to the sleeve at a downstream end thereof, the rod extending substantially parallel to the sleeve axis, eccentrically relative to the sleeve. The eccentric location of the rod enables a tubular suction member to be inserted over or along the rod without unduly limiting the cross-sectional area of a suction channel defined by the tubular member. Thus, greater amounts of debris may be removed more quickly through the tubular member from the filter body. In contrast to prior art filter devices used in debris removal during vascular surgery, the filter device of the present invention may be left in position during the entire operation. There is no need to remove the device during the operation to clear the filter body. The coupling element enables connection of the debris removal device to the filter body and removal of debris continuously during the vascular surgical operation.

A method for collecting intravascular debris comprises, in accordance with the present invention, inserting a filter or

collector body in a collapsed configuration into a blood vessel of a patient, expanding the filter body in the blood vessel from the collapsed configuration to an expanded use configuration wherein the filter body tapers down from a maximum cross-sectional area to a minimal cross-sectional area, and positioning the expanded filter body in the blood vessel so that the minimal cross-sectional area is disposed downstream of the maximum cross-sectional area. Vascular debris is caught in the expanded filter body positioned in the blood vessel, and thereafter a distal end portion of an elongate debris removal instrument is used to remove debris from the filter body while the filter is deployed in the blood vessel.

Where the filter is more or less permanently deployed in the blood vessel, the debris removal instrument is inserted into the blood vessel after the positioning of the filter body and the collecting of debris therein. The distal end portion of the instrument is removably coupled to the filter body, and the instrument is operated to remove debris from the filter body. After the removal of debris from the filter body, the instrument is extracted from the blood vessel, while the filter body is maintained in the blood vessel to catch further intravascular debris. Another cleaning of the filter body pursuant to the same technique may be performed at a subsequent time.

Where the filter body has an access port disposed proximate to the minimal cross-sectional area, the operating of the debris removal instrument includes removing debris from the filter body via the access port.

Where the filter body is provided at the minimal cross-sectional area with a coupling element, the coupling of the distal end portion of the instrument to the filter body includes removably connecting the distal end portion of the instrument to the coupling element.

The method may additionally comprise removably fastening a rod to the coupling element at a downstream end thereof, the instrument being guided along the rod during insertion of the instrument into the blood vessel.

The operating of the instrument generally includes the application of suction to pull debris from the filter body. In that case, the filter body may be liquid impermeable at least in a region about the access port to facilitate the generation of a vacuum force in the filter body and to decrease associated blood loss.

The present invention facilitates vascular surgery by enabling the continuous removal of vascular debris downstream of the surgical site. The filter body need not be removed from the vascular system of the patient until the operation has been completed. The operation need not be interrupted in order to permit the removal and cleaning of a filter basket.

Where the filter body is permanently deployed, the present invention enables a periodic minimally invasive cleaning of the filter and thus reduces complications otherwise attendant on the use of such a permanent vascular filter.

Thus, an intravascular filter in accordance with the present invention, with a specific clot removal channel at the apex of the filter, in conjunction with a slidable and detachable two piece clot extraction mechanism (consisting of the thrombectomy device/tube that fits over or into the chimney) permits the filtration of clots from the vascular system, while also permitting the extraction of these captured clots through a simple system. This is performed without the need for bulky, concentric associated catheters which will preclude the use of such technology for permanent placement and/or decrease the lumen size available for clot removal.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic side elevational view, on an enlarged scale, of an intravascular filter device in accordance with the present invention.

FIG. 2 is partially a schematic side elevational view similar to **FIG. 1** and partially a cross-sectional view of the filter device of **FIG. 1**, diagrammatically showing coupling of a debris removal device to the filter for purposes of removing intravascular debris collected in the filter device.

FIG. 3A is a schematic longitudinal cross-sectional view, on an enlarged scale, of the filter device of FIGS. 1 and 2, showing the device prior to and during an initial stage of an insertion procedure.

FIGS. 3B–3D are schematic longitudinal cross-sectional views, on an enlarged scale, of the filter device of FIGS. 1 and 2, showing successive steps in the utilization of the filter device and a debris removal device.

FIG. 4 is a schematic side elevational view, on an enlarged scale, of a thrombectomy device which may be used to remove clot and other vascular debris from the filter device of FIGS. **1** and **2**.

FIG. 5 is a cross-sectional view taken along line V—V in FIG. **4**.

FIG. 6 is a cross-sectional view taken along line VI—VI in FIG. **4**.

FIG. 7 is a schematic longitudinal cross-sectional view of another intravascular filter device in accordance with the present invention.

FIG. 8 is an end elevational view of the intravascular filter device of **FIG. 7**, taken from the right hand side in **FIG. 7**.

FIG. 9 is a schematic side elevational view of an additional intravascular filter device in accordance with the present invention.

FIG. 10 is a schematic elevational view of a rim element of the filter device of **FIG. 10**, showing the rim element in a laid out configuration.

FIG. 11 is a schematic side elevational view of yet another intravascular filter device in accordance with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As illustrated in **FIGS. 1 and 2**, an intravascularly deployable filter device **10** for collecting intravascular debris comprises a conical filter body **12** made of a plurality of longitudinally extending prongs or tines **11**. Optional, transversely positioned circular reinforcement ribs **13** may be provided, as indicated by phantom lines, to create a mesh or net like material. In order to reduce the amount of material in the filter device, ribs **13** are preferably omitted.

Filter body **12** is expandable from a collapsed insertion configuration (not shown) to an expanded use configuration depicted in **FIG. 1**. The use configuration of filter body **12** tapers down from a maximum cross-sectional area in a plane **P1** to a minimal cross-sectional area in a plane **P2** at a downstream end **14** of body **12**.

As shown in **FIG. 2**, filter body **12** is provided at the downstream end with an access opening **16**. A coupling element or access port **18** is connected to body **12** at downstream end **14**. Coupling element **18** is designed to cooperate with a distal end **20** of an elongate debris removal instrument **22** to removably connect the instrument to filter body **12** so that the instrument can traverse access opening **16** to remove debris from body **12** after disposition of the

intravascularly deployable filter device **10** inside a blood vessel of a patient.

Coupling element **18** takes the form of a sleeve which is beveled to taper down from a maximal transverse dimension in plane P2 at an upstream end to a minimal transverse dimension at a downstream end **24**. The beveling or tapering of coupling sleeve **18** is especially useful in locating or guiding distal end **20** of debris removal instrument **22** into juxtaposition with downstream end **14** of filter body **12** during a shifting of instrument **22** in the upstream direction towards filter body **12**. More specifically, debris removal instrument **22** generally includes a tubular outer member **26** which is slid over coupling sleeve **18** during a connecting of distal end **20** of instrument **22** to filter body **12**. In a region about its maximal cross-sectional area, coupling sleeve **18** is snugly received in tubular member **26**. A cutting element **28** is received in tubular member **26**. Cutting element **28** is optionally longitudinally shiftable in a distal direction (to the right in FIGS. **1** and **2**) through the tubular member and into filter body **12** through access opening **16** thereof. Other alternative types of cutting elements are possible, where the cutting element is not necessarily longitudinally shiftable through tubular member **26**, for example, in the case of a rotary cutter.

A rod **30** is connected or is connectable to coupling sleeve **18** at downstream end **24** thereof for purposes of deploying or removing filter device **10** and guiding instrument **22** to device **10** after the installation thereof at a desired intravascular site, as described in greater detail hereinafter. Rod **30** extends parallel to an axis **32** of coupling sleeve **18**, eccentrically relative to the coupling sleeve.

Filter body **12** is provided at least in a region about access opening **16** with a web or film **34** which renders the filter body liquid impermeable at the downstream end **14**. Where suction is applied to tubular member **26** to draw debris from filter body **12** into the debris removal instrument **22**, web or film **34** serves to enhance the suction action by blocking blood in the region about access port **16** from entering distal end **20** of tubular member **26**. To prevent debris from exiting filter body **12** through access opening **16** when debris removal device **22** is not connected to coupling sleeve **18**, a flap or door **36** may be provided in sleeve **18** or on filter body **12** at downstream end **14** thereof.

In the embodiment of FIGS. **1** and **2**, web or film **34** extends in an axial or longitudinal direction only partially along tines **11**. However, the embodiment of FIGS. **1** and **2** may be modified so that web or film **34** is axially or longitudinally coextensive with tines **11** or extends beyond the ends of tines **11**.

Given the small size of the filter device **10**, particularly the small diameter of sleeve **18**, it is difficult to attach many tines **11** to the upstream end of sleeve **18**. There is simply not enough space to form many attachments. In order to facilitate manufacture, tines **11** may be connected to sleeve **18** indirectly via web or film **34**. In that event, web or film **34** is an integral and necessary part of filter body **12**.

Filter device **10** may be utilized as a permanent vascular filter. In that case, filter body **12** is provided with a plurality of outwardly turned barbs **38** which serve to anchor the filter device in a vein or artery with cone shaped body **12** pointing in a downstream direction. Successive stages in the use of filter device **10** as a permanent vascular filter are depicted in FIGS. **3**A–**3**D.

Filter device **10** is deployed with the aid of tubular member **26**, which also assists in the removal of vascular debris collected by filter device **10**. Alternatively, another tubular sheath member (not illustrated) may be used to deploy filter device **10**.

As illustrated in FIG. **3**A, filter device **10** used as a permanently deployed device is initially disposed in a collapsed configuration inside tubular debris removal member **26**, and particularly at a distal end of this tubular member. Rod **30** (FIGS. **1** and **2**) takes the form of a wire **42** provided at a distal end with a hook **44** which traverses an aperture (not shown) disposed in a finger **46** extending in a proximal direction from coupling sleeve **18**.

A distal end portion of the assembly illustrated in FIG. **3**A is inserted into a blood vessel BV, as shown in FIG. **3**B. At a predetermined destination or installation site in blood vessel BV detected by conventional radiographic or other techniques, rod **30** is pushed in the distal direction relative to outer tubular member **26** to eject filter device **10** from member **26** into blood vessel BV. Upon ejection, filter device **10** opens under internal spring forces to assume the expanded configuration shown in FIGS. **1**, **2** and **3**B). Rod or wire **42** is then used to properly position filter device **10** in blood vessel. In particular, rod or wire **42** is drawn in the proximal direction to induce barbs **38** to pierce a wall **52** of blood vessel BV. Upon the lodging of barbs **38** in wall **52** and the concomitant anchoring of filter device **10** to blood vessel BV at or about the predetermined installation site, rod or wire **42** is pulled out of blood vessel.

During a subsequent period, filter body **12** acts to catch or collect pieces of vascular debris **54** such as clot bits floating downstream in blood vessel BV. When filter body **12** has been filled to some predetermined degree, rod or wire **42** is reinserted into blood vessel BV, as depicted in FIG. **3**C and manipulated to attach hook **44** to finger **46**. Rod or wire **42** serves in part to stabilize and hold filter device **10** during coupling of debris removal device **22** to sleeve **18** and optionally during a subsequent filter cleaning operation. Rod or wire **42** serves also as a guidewire about which tubular debris removal member **26** (FIGS. **2** and **3**D) is guided during insertion of that member into blood vessel BV.

After the positioning of sleeve **18** in the distal end **20** of tubular member **26**, cutting element **28** (FIG. **2**) is shifted in the distal direction through sleeve **18** and access opening **16** into the downstream end **14** of filter body **12**. As shown in FIG. **3**D, cutting element **28** particularly takes a tapered form **56** which facilitates the locating of cutting element relative to access opening **16** during a drawing of cutting element **28** in a proximal direction to sever clot material and vascular debris. Tubular member **26** is operatively connected at a proximal end to a suction source **58** whereby debris is drawn into tubular member **26** after the ejection of tapered cutting element **56** from the upstream end of sleeve **18** into filter body **12**. Subsequently, cutting element **56** is drawn back into sleeve **18** owing to a proximally directed force exerted via a hollow rod **60** connected to cutting element **56**. Cutting element **56** cooperates with an inner, upstream circular edge (not designated) of sleeve **18** in severing, in a scissors-like action, the debris sucked into sleeve **18**.

Rod **60** communicates with a pressurizable irrigant (saline) source **62**, whereby liquid is fed to sleeve **18** and tubular member **26** upstream of the severed debris, thereby facilitating the production of a pressure gradient tending to move the severed material in a proximal direction through tubular member **26** towards suction source **58**. Because source **62** is pressurizable, the upstream side of the severed material may be positively pressurized to any degree necessary to eject the severed material from tubular member **26**

and hence from blood vessel BV. Thus, device **22** is impossible to clog and is capable of removing all collected debris from filter body **12**.

As mentioned above with reference to FIGS. **1** and **2**, device **10** may be used as a temporary filter inserted intravascularly for purposes of collecting debris generated during a vascular operation upstream of the deployment position of the filter. In the case of a temporary filter, barbs **38** are omitted, while rod **30** is permanently connected to coupling sleeve **18**. Clot removal device **22** may still take the form described above with reference to FIG. 3D.

FIGS. **4–6** depict a particular thrombectomy device **102** which may be utilized to remove clot and other vascular debris from filter body **12**, whether filter device **10** is disposed permanently or temporarily in a blood vessel BV. It must be understood, however, that virtually any type of thrombectomy or vascular debris removal instrument may be used in conjunction with filter device **10** to extract vascular debris collected in filter body **12**. The particular form of the thrombectomy instrument is not considered to be especially pertinent to the invention.

As discussed above with reference to tapered cutting element **56**, thrombectomy device **102** is sufficiently narrow to be inserted into coupling sleeve **18** for enabling removal of clot material from filter body **12** by device **102**. Thrombectomy device **102** may be deployed by itself or with the aid of tubular debris removal member **26** or another sheath member. Accordingly, in the discussion below, reference is made in the alternative to sleeve **18** and tubular debris removal member **26**.

As depicted in FIGS. **4–6**, thrombectomy device **102** comprises a cylindrical cutting head **106** having a longitudinal axis **108** and a rounded distal end **109**. An elongate drive rod **110** is eccentrically attached at a distal end to cutting head **106** at a location spaced from longitudinal axis **108**. Drive rod **110** extends parallel to axis **108**. Cutting head **106** is provided on a proximal side with a cutout **112** in part for enabling a drawing of thrombus in a proximal direction from filter body **12** into sleeve **18** (where the distal end of debris removal member **26** surrounds sleeve **18**) or a distal end of debris removal member **26** (where the distal end of tubular member **26** is inserted into sleeve **18**) upon a partial ejection of cutting head **106** from the distal end of sleeve **18** or tubular member **26** during a thrombectomy procedure. The material drawn into sleeve **18** or tubular member **26** is severed by cutting head **106** in a scissors-like action upon a drawing of cutting head **106** via drive rod **110** into sleeve **18** or the distal end of tubular member **26**.

Cutting head **106** has a semicylindrical outer surface **116** which closely conforms to an inner surface of sleeve **18** or tubular member **26**, depending on whether tubular member **26** fits over or into sleeve **18**. Surface **116** may begin at a point which is longitudinally spaced from the most proximal end point **118** of cutting head **106** and is located between a maximal transverse cross-section of cutting head **106** (at line V—V in FIG. **4**) and proximal end point **118**. Surface **116** extends generally from drive rod **110** on one side of cutting head **106** to cutout **112** on an opposite side of cutting head **106** and serves to ensure a locating of drive rod **110** eccentrically relative to sleeve **18** or tubular member **26** upon the drawing of cutting head **106** into sleeve **18** or the distal end of tubular member **26**. This locating is effectuated by the close fit of the cutting head into sleeve **18** or the tubular member **26** and the inability of the cutting head to migrate in a transverse or radial direction relative to the sleeve **18** or member **26** once semicylindrical surface **116** of cutting head **106** has been drawn into the sleeve or tubular member **26**. Also, the construction of the proximal end portion of cutting head **106**, as tapered from the maximal cross-section (line V—V) to proximal end point **118**, enables an unobstructed and smooth guiding of the cutting head **106** into sleeve **18** or tubular member **26**, without catching.

Drive rod **110** has a longitudinally extending lumen **120** (FIGS. **5** and **6**) and extends into cutting head **106** along an inner surface (not designated) thereof to a distal end of the cutting head. At that distal end, drive rod **110** is provided with an irrigation outlet **122** which communicates with lumen **120**. In general, irrigation outlet **122** is provided at a most distal position of device **102** so that irrigation fluid is always delivered to tubular member **26** at a point upstream of any severed mass **124** in tubular member **26**.

During a debris removal procedure, a distal end portion of tubular member **26** is fitted onto or into coupling sleeve **18**. Drive rod **110** is provided at a proximal end with a handle **128** for facilitating the manipulation of the device **102** during the procedure. Cutting head **106** is ejected from the distal end of sleeve **18** or tubular member **26**. Suction applied to tubular member **26** via a suction port pulls thrombus or other vascular debris from the patient into tubular member **26** via a window partially defined by cutout **112** and partially by a leading or upstream edge of sleeve **18** or tubular member **26**. Subsequently, cutting head **106** is retracted into sleeve **18** or tubular member **26**, thereby severing clot mass **124**. Cutting head **106** also closes the upstream end of sleeve **18** or tubular member **26** upon the termination of the proximally directed cutting stroke. Suction is applied continuously by suction source **58** (FIG. **3D**) at a proximal end of tubular member **26**, while irrigation fluid is fed to cutting head **106** and consequently to tubular member **26** via lumen **120** and irrigation outlet or port **122**. The feeding of fluid upstream of severed clot mass **124** and a continued application of suction downstream of the severed material enables the formation of a pressure differential across the severed mass, thereby greatly facilitating the removal of the severed mass from tubular member **26** and from the patient. Fluid upstream of the severed thrombus material may be positively pressurized to any degree necessary to ensure the extraction of severed clot mass. An alternative procedure is to mechanically pull clot out of tubular member **26** via drive rod **110** and cutting head **106**. Consequently, drive rod **110** may be a solid, but flexible, member with irrigation outlet or port **122** omitted.

As depicted in FIGS. **7** and **8**, another intravascularly deployable filter device **132** for collecting intravascular debris comprises an essentially conical body **134** made of a plurality of triangular fingers or prongs **136** connected on one side to an upstream end of a tapered cylindrical port element or coupling member **138**. Filter body **134** is expandable from a collapsed insertion configuration (not shown) to an expanded use configuration depicted in FIGS. **7** and **8**. The use configuration of filter body **134** tapers down from a maximum cross-sectional area in a plane P3 to a minimal cross-sectional area in a plane P4 at the upstream end of cylindrical port element **138**. As described above, port element **138** provides access to filter body **134** for facilitating or enabling removal of vascular debris which has collected in filter body **134**. A head **106** of debris removal or thrombectomy device **102** discussed hereinabove with reference to FIGS. **4–6** is inserted through port element **138** into a downstream end of filter body **134** and cooperates with the upstream end or edge of port element **138** to sever and remove pieces of debris from the filter body.

As shown in FIG. **8**, the upstream rim or edge of port element **138** defines an access port **140**. As described above

with reference to FIG. 2, port element **138** is designed to cooperate with a distal end **20** of an elongate debris removal instrument **22** to removably connect the instrument to filter body **134** so that the instrument can traverse access port **140** to remove debris from body **134** after disposition of the intravascularly deployable filter device **132** inside a blood vessel of a patient. As further described above with reference to FIG. **2**, a rod **30** is connected or is connectable to port element **138** at a downstream end thereof for purposes of deploying or removing filter device **132** and guiding instrument **22** to device **10** after the installation thereof at a desired intravascular site.

Filter body **134** may be provided at least in a region about access port **140** with a web or film **142** which renders the filter body liquid impermeable at its downstream side. Web or film **142** enhances the transmission of suction forces during a debris removal operation, as discussed above, and may be as long as or longer than fingers **136**. To prevent debris from exiting filter body **134** through access port **140** when debris removal device **22** (FIG. **2**) is not connected to port element **138**, a flap or door **144** may be provided in port element **138** or on filter body **134**.

Fingers **136** are parts of a continuous, zig-zag wire member (reference numeral **134**) which is folded to form fingers **136**, bonded at one side to sleeve **138** and spring biased to assume the opened configuration of FIGS. **7** and **8**.

As depicted in FIG. **9**, an additional intravascularly deployable filter device **146** for collecting intravascular debris comprises a conical filter or collector body **148** defined by a plurality of longitudinally extending prongs or tines **150** connected at a downstream end to a circular edge or rim **152** of a tapered cylindrical port member or coupling sleeve **154**. Conical body **148** is further formed by a resilient zig-zag terminal element **156** connected to prongs **150** at ends thereof opposite coupling sleeve **154**. As illustrated in FIG. **10**, zig-zag element **156** comprises a plurality of folds **158** which are staggered relative to one another so that successive downstream bend points **160** are longitudinally spaced from one another and so that successive upstream bend points **164** are longitudinally spaced from one another, as measured against a longitudinal axis **162** of filter device **146**. This staggering of folds **158** serves to effectively decrease the maximum transverse cross-sectional area of filter device **146** by longitudinally distributing the material of the filter body **146** and thereby reducing the accumulation of construction materials.

Filter body **146** is expandable from a collapsed insertion configuration (not shown) to an expanded use configuration depicted in FIG. **9**. The use configuration of filter body **148** tapers down from a maximum cross-sectional area in a plane **P5** to a minimal cross-sectional area in a plane **P6** at the upstream end of coupling sleeve **154**. Coupling sleeve **154** provides access to filter body **148** for facilitating or enabling removal of vascular debris which has collected therein. Again, a head **106** (FIG. **4**) of debris removal or thrombectomy device **102** discussed hereinabove with reference to FIGS. **4–6** is inserted through coupling sleeve **154** and cooperates with the upstream end or edge of coupling sleeve **154** to sever and remove pieces of debris from the filter body.

Filter body **148** is provided with a web or film **166** which renders the filter body liquid impermeable at least at its downstream side. Web or film **166** could be made long enough to cover or envelope prongs **150** and zig-zag element **156**. Web or film **166** enhances the transmission of suction forces during a debris removal operation, as discussed above. To prevent debris from exiting filter body **148** when debris removal device **22** (FIG. **2**) is not connected to coupling sleeve **154**, a flap or door (not shown) may be provided in the coupling sleeve or on filter body **148**.

In an alternative construction of filter device **146**, prongs **150** may be fixed indirectly to sleeve **154** via membrane **166**. More specifically, prongs **150** may be connected at their downstream ends to membrane **166** at longitudinally staggered connection points (not shown). The staggering of the connection points serves to distribute the material of the filter device to minimize the maximum external diameter thereof.

FIG. **11** depicts an intravascularly deployable filter device **168** which represents a modification of the device of FIGS. **7** and **8**. Device **168** includes a port element or coupling sleeve **170** connected at an upstream edge to a conical film of a membrane **172** by an O-ring **171**. A resilient zig-zag filter element **182**, which is configured as discussed above with respect to FIG. **10**, is fixed at a plurality of longitudinally staggered downstream fold points or bends **176** to membrane **172**. Filter element **182** has a plurality of folds **180** which exhibit longitudinally staggered upstream fold points or bends **174**, as well as longitudinally staggered downstream fold points or bends **176**. The staggering of fold points **174** and **176** serves to distribute the material of filter element **182**, thereby minimizing the maximum transverse dimension of filter device **168**. In its opened configuration, filter element **182** defines a conical extension of membrane **172**. It is to be noted, however, that membrane **172** may completely overlap filter element **182** so that the zig-zag filter element is surrounded by membrane **172**.

Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. For example, the coupling element or access port at the downstream end of a filter device in accordance with the present invention may take forms other than a beveled sleeve. The coupling element enables or facilitates the guidance of a debris removal device (e.g., thrombectomy device) through the access opening into the filter body. This function could be performed, for instance, by three or four longitudinally extending parallel rods connected to the filter body in a circumferentially spaced relation about the access opening. These rods define a longitudinal space for receiving a thrombectomy device and guiding that device through the access opening into the filter body. One such rod may be sufficient, if provided with means for aligning a distal end of a debris removal instrument with the access opening and maintaining the debris removal instrument coupled to the filter device during a debris removal procedure.

Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. An intravascularly deployable device for collecting intravascular debris, comprising a collector body expandable from a collapsed insertion configuration to an expanded use configuration, said use configuration of said body tapering down from a maximum cross-sectional area to a minimal cross-sectional area at a downstream end of said body, said body being provided at said downstream end with an access port to removably connect an elongate debris removal instrument to said body so that said instrument can traverse said access port to remove debris from said body after

disposition of the intravascularly deployable device inside a blood vessel of a patient, said access port taking the form of a sleeve extending in a downstream direction from said body said sleeve being beveled to taper down from a maximal transverse outside dimension at an upstream end to a minimal transverse outside dimension at a downstream end.

2. The device defined in claim 1 wherein said sleeve has a longitudinal axis, further comprising a connector disposed on said sleeve at the downstream end thereof for enabling a connection of a rod to said sleeve so that said rod extends substantially parallel to said axis, eccentrically relative to said sleeve.

3. The device defined in claim 2 wherein said body is liquid impermeable at least in a region about said access port.

4. The device defined in claim 3 wherein said body includes a plurality of prongs or tines, further comprising a web provided on said body at least at the downstream end thereof to render said body liquid impermeable in said region about said access port.

5. The device defined in claim 2 in said body is provided at a location spaced from said access port with means for fixing said body to the wall of the blood vessel.

6. The device defined in claim 2. further comprising a flap door mounted to one of said body and said sleeve for preventing debris from spontaneously exiting said body through said access port.

7. The device defined in claim 1 wherein said sleeve has a longitudinal axis, further comprising a rod connected to said sleeve at a downstream end thereof, said rod extending substantially parallel to said axis, eccentrically relative to said sleeve.

8. The device defined in claim 7 wherein said body is liquid impermeable at least in a region about said access port.

9. The device defined in claim 8 wherein said body includes a plurality of prongs or tines, further comprising a web provided on said body at least at the downstream end thereof to render said body liquid impermeable in said region about said access port.

10. The device defined in claim 7, further comprising a flap door mounted to one of said body and said access port for preventing debris from unintentionally exiting said body through said access port.

11. The device defined in claim 1 wherein said body is liquid impermeable at least in a region about said access port.

12. The device defined in claim 11 wherein said body includes a plurality of prongs or tines, further comprising a web provided on said body at the downstream end thereof to render said body liquid impermeable in said region about said access port.

13. The device defined in claim 1 wherein said body is provided at a location spaced from said access port with means for fixing said body to the wall of the blood vessel.

14. The device defined in claim 1, further comprising a flap door mounted to one of said body and said access port for preventing debris from unintentionally exiting said body through said access port.

15. The device defined in claim 1 wherein said sleeve has a longitudinal axis and is beveled from one side to an opposite side at an angle to said axis.

16. An intravascularly deployable device for collecting intravascular debris, comprising a collector body expandable from a collapsed insertion configuration to an expanded use configuration, said use configuration of said body tapering down from a maximum cross-sectional area to a minimal cross-sectional area at a downstream end of said body, said body being provided at said downstream end with an access sleeve to removably connect an elongate debris removal instrument to said body so that said instrument can traverse said sleeve to remove debris from said body after disposition of the intravascularly deployable device inside a blood vessel of a patient, said sleeve having a longitudinal axis, a rod being connected to said sleeve at a downstream end thereof, said rod extending substantially parallel to said axis, eccentrically relative to said sleeve.

17. The device defined in claim 16 wherein said sleeve is beveled to taper down from a maximal transverse dimension at an upstream end to a minimal transverse dimension at a downstream end.

18. An intravascularly deployable assembly for collecting intravascular debris, comprising:

a collector body expandable from a collapsed insertion configuration to an expanded use configuration, said use configuration of said collector body tapering down from a maximum cross-sectional area to a minimal cross-sectional area at a downstream end of said collector body, said collector body being provided at said downstream end with a sleeve extending from said collector body in a downstream direction; and

an elongate tubular debris removal member removably connected to said collector body via said sleeve, said sleeve being substantially shorter than said tubular debris removal member and not substantially longer than said collector body, said sleeve being inserted in an upstream end of said tubular debris removal member.

19. The assembly defined in claim 18 wherein said sleeve is beveled to taper down from a maximal transverse dimension at an upstream end to a minimal transverse dimension at a downstream end.

20. The assembly defined in claim 19 wherein said sleeve has a longitudinal axis, further comprising a connector disposed on said sleeve at the downstream end thereof for enabling a connection of a rod to said sleeve so that said rod extends substantially parallel to said axis, eccentrically relative to said sleeve.

21. The assembly defined in claim 18, further comprising an elongate debris removal instrument slidably inserted through said tubular debris removal instrument so that said instrument traverses said sleeve to remove debris from said collector body while the collector body is in place inside a blood vessel of a patient.

22. The assembly defined in claim 18 wherein said body is liquid impermeable at least in a region about said access port.

23. The assembly defined in claim 18 wherein said body is provided at a location spaced from said access port with means for fixing said body to the wall of the blood vessel.

24. The assembly defined in claim 18 wherein said sleeve is slidably inserted into the distal end of said tubular debris removal member.

25. A method for collecting intravascular debris, comprising:

inserting, into a blood vessel of a patient, a tubular member carrying a filter device in a collapsed insertion configuration in a distal end of said tubular member;

after insertion of said tubular member into the patient's blood vessel, ejecting said filter device from said distal end of said tubular member;

expanding the ejected filter device from said collapsed insertion configuration to an expanded use

configuration, said use configuration of said filter device tapering down from a maximum cross-sectional area to a minimal cross-sectional area at a downstream end of said filter device, said filter device being provided at said downstream end with a sleeve extending from said filter device in a downstream direction, said sleeve being substantially shorter than said tubular member and not substantially longer than said filter device;

inserting an elongate debris removal instrument through said tubular member so that an operative head of said instrument is inserted through said sleeve into said filter device;

operating said instrument to remove collected vascular debris from said filter device; and

maintaining said sleeve inserted in said distal end of said tubular member during the insertion of said instrument and during operation of said instrument.

26. The method defined in claim **25**, further comprising:

removing said instrument and said tubular member from the patient after effectively clearing debris from said filter device; and

leaving said filter device in said blood vessel after removal of said instrument and said tubular member.

27. The method defined in claim **25**, further comprising removably fastening a rod to said sleeve at a downstream end thereof, said instrument being guided along said rod during insertion of said instrument through said tubular member.

28. The method defined in claim **27** wherein said rod is fastened eccentrically to said sleeve and extends eccentrically relative to said instrument during the removing of debris from said filter device.

29. The method defined in claim **25** wherein said filter device is liquid impermeable at least in a region about said sleeve, the operating of said instrument including applying suction to debris in said filter device via said instrument, the liquid impermeability of said filter device in said region facilitating a sucking of debris from said filter device.

30. A method for collecting intravascular debris, comprising:

deploying a collector body in a blood vessel of a patient so that said body tapers down from a maximum cross-sectional area to a minimal cross-sectional area at a downstream end of said body and so that a sleeve provided on said collector body at said downstream end thereof extends in a downstream direction from said body, said sleeve having a free end opposite said collector body, said free end being disposed completely within said blood vessel;

after the deploying of said collector body in said blood vessel, collecting vascular debris in said collector body;

after the collecting of the vascular debris in said collector body, removably connecting an elongate debris removal instrument to said collector body via said sleeve; and

operating the connected debris removal instrument to remove the collected vascular debris from said collector body via said sleeve.

31. The method defined in claim **30** wherein said debris removal instrument includes a tubular member, the connecting of said debris removal instrument to said collector body via said sleeve including inserting a distal end of said tubular member over said sleeve.

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